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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,494

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Joel Q. Xue

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EXAMINER

PATEL, NATASHA

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,494

Applicant(s)

XUE ET AL.

Examiner

Natasha N. Patel

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed on June 2, 2006 have been fully considered. By this amendment, Claims 1-20 are pending.

Response to Arguments

2. Applicant's arguments filed June 2, 2006 have been fully considered but they are not persuasive. Regarding independent claims 1, 16, and 20, applicant argues that Cohen fails to disclose a morphology shape descriptor. Applicant further argues that the alternan morphology index does not constitute a morphology shape descriptor. As the examiner currently understands independent claims 1, 16, and 20, the morphology shape descriptor acts to map each representative beat to a value, which is used to assess cardiac repolarization abnormality. The morphology index of Cohen acts as a mapping function to assess cardiac stability. As discussed in the previous office action, the correlation between ST-T wave alternation and cardiac stability can be used to assess cardiac repolarization.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 7, 11, 15-17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen et al. (US Patent 4,802,491).

5. Regarding Claim 1, Cohen discloses deriving a total quantity of representative beats of the at least one electrocardiogram signal (see series of heart beats col. 2, lines 9-13); using at least one morphology shape descriptor (alternating energy) to determine a total quantity of values (sample points) representing the total quantity of representative beats (see col. 2, lines 14-21); and using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality (see col. 10, lines 3-18). The examiner considers that the correlation between ST-T wave alternation and cardiac stability can be used to assess cardiac repolarization abnormality because repolarization occurs during the T wave and that is the region being evaluated by Cohen.

6. Regarding Claims 2 and 17, Cohen discloses that the total quantity of representative beats comprises at least one beat representative of each lead of the at least one electrocardiogram signal (see col. 7, lines 44-49). The examiner considers since the three leads recorded three separate electrocardiograms and sample beats were taken from all of the electrocardiograms, then representative beats from all three leads were present in the sample.

7. Regarding Claim 7, Cohen discloses normalizing at least some of the values of the total quantity of values (see col. 2, lines 17-21).

8. Regarding Claim 11, Cohen discloses tagging at least one value of the total quantity of values with a marker (see col. 2, lines 50-54).

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9. Regarding Claim 15, Cohen discloses displaying data corresponding to at least one (see col. 10, lines 47-56). Variability in waveform morphology corresponds to the ECG and the matrix of data is a method of displaying this data.

10. Regarding Claim 16, Cohen discloses deriving a total quantity of representative beats of the at least one electrocardiogram signal (see series of heart beats col. 2, lines 9-13); using at least one morphology shape descriptor (alternating energy) to determine a total quantity of values (sample points) representing the total quantity of representative beats (see col. 2, lines 14-21); and generating a template using at least one value corresponding to at least one of the representative beats (see col. 3, lines 11-13); comparing the template and at least one value corresponding to at least one other of the representative beats (see blocks 16-18, Figure 1); and using the comparison to determine whether a cardiac repolarization abnormality exists (see col. 3, lines 18-20).

11. Regarding Claim 20, Cohen discloses a device comprising: means for generating a total quantity of representative beats of the at least one electrocardiogram signal (see HP 3968a FM tape recorder, col. 2, lines 38-42); means for using at least one morphology shape descriptor to determine a total quantity of values representing the total quantity of representative beats (see Masscomp MC500 computer, col. 2, lines 42-54); and means for using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality (see two-dimensional matrix, col. 3, lines 31-40). In other words, the tape recorder records the ECG signals and provides the representative beats to the computer, which takes sample values from the data

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segments and uses matrices along with the alternating ECG morphology index to determine whether or not abnormal repolarization exists.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 3-6 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Thiagarajan et al. (US Patent 6,983,183).

14. Regarding Claim 3, Cohen discloses an iterative, adaptive template (see col. 2, lines 57-61). Cohen does not elaborate on how this template is generated. Thiagarajan discloses generating a template using at least one value (data) corresponding to at least one of the representative beats (see last six to eight beats, col. 6, lines 34-40).

Thiagarajan also discloses comparing the template and at least one value corresponding to at least one other of the representative beats (see col. 6, lines 54-61).

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use Thiagarajan's technique to generate an adaptive template for more accurate and up-to-date comparisons.

15. Regarding Claim 4, Cohen discloses that a cardiac repolarization abnormality exists if a variation between the template and the at least one value corresponding to at least one other of the representative beats is greater than a threshold value (see col. 9, lines 48-52).

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16. Regarding Claim 5, Cohen discloses adjusting the alternation energy based at least in part on a level of noise in the at least one electrocardiogram signal (see col. 7, lines 10-23). Cohen does not disclose adjusting the threshold value due to the level of noise. However, it is well known and common in signal processing to adjust values to accommodate for noise. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to adjust the threshold value based on the level of noise, especially since the other values, which are being compared to the threshold value, have been adjusted under the same circumstances. Being consistent in this manner, allows for a more accurate comparison between the ECG signal values and the threshold.

17. Regarding Claim 6, Thiagarajan discloses altering the template based at least in part on the at least one value corresponding to the at least one other of the representative beats (see col. 6, lines 37-46). The examiner considers the periodic generation of templates is an alteration of the previous template because the generation of the template takes into account a changing morphology, which indicates an alteration.

18. Regarding Claim 12, Cohen discloses a marker (see col. 3, lines 40-44), but he does not disclose that the marker is a measurement that does not change over time. Thiagarajan discloses a marker that does not change over time (see col. 6, lines 8-13). The position and magnitude of the R-wave is a measurement that will not change considerably over time. Thus, it would have been obvious to one of ordinary skill in the

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art at the time of the invention to use such a marker to detect abnormalities in the ECG signals to be evaluated for cardiac repolarization.

19. Regarding Claim 13, Cohen discloses that the marker is a measurement that changes over time (see col. 3, lines 40-44). The examiner considers that the different values are indicative of changing measurements and 'one particular time in its evolution' refers to a constant time interval at which these measurements are taken.

20. Regarding Claim 14, Cohen discloses using the marker as part of a discriminator of cardiac repolarization abnormality (see col. 3, lines 26-29). The marker-based analysis procedure described helps to detect and quantify alternation in waveform morphology. The examiner believes since alternation indicates repolarization abnormalities, the marker-based analysis is essentially indicating repolarization abnormalities.

21. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (US Patent 4,802,491) in view of Arnold et al. (US Patent 5,713,367).

22. Regarding Claims 8 and 18, Cohen discloses the selection and analysis of appropriate data segments (see col. 2, lines 40-43). However, Cohen does not elaborate on the selection process. Arnold discloses a first electrocardiogram signal representative of a first duration of time and a second electrocardiogram signal representative of a second duration of time, and wherein the first duration of time and the second duration of time are non-continuous (see col. 5, lines 42-52). The examiner considers that the characterization of only portions of the recorded ECG data means that there will be a portion of the signal representing one duration of time and another

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portion of the signal representing another duration of time. The examiner considers that a portion of a signal is still a signal. It would have been obvious to one of ordinary skill in the art at the time of the invention to select various segments of the ECG signals for analysis since choosing two contiguous segments may inadvertently increase the chances of not noticing an abnormality.

23. Claims 9-10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (US Patent 4,802,491) and Arnold et al. (US Patent 5,713,367) as applied to Claims 8 and 18 above in view of DePasquale et al. (US Patent 6,847,840).

24. Regarding Claims 9 and 19, Arnold discloses administering a pharmacological agent that stresses the heart of the patient (see col. 3, lines 52-56) and obtaining an ECG signal (see col. 10, lines 10-23). Arnold does not disclose determining variations between ECG signals before and after administering the drug. DePasquale discloses introducing pharmacological intervention; obtaining the at least one electrocardiogram signal from the patient, the at least one electrocardiogram signal comprising a first electrocardiogram signal comprising beats prior to the administration of the pharmaceutical drug (see pre-dose curve) and a second electrocardiogram signal comprising beats after the administration of the pharmaceutical drug (see post-dose curve); and determining a variation between values of the total quantity of values that correspond to the first electrocardiogram signal and values of the total quantity of values that correspond to the second electrocardiogram signal (see col. 2, lines 25-36). One of ordinary skill in the art at the time of the invention would have found it obvious to compare the values from the first and second ECG signals to understand which

variations were attributed to the drug and which variations may be attributed to a problem in the heart, thereby improving signal processing and improve the accuracy of measuring alternans which in turn help detect abnormal cardiac repolarization (see '367, Abstract: 2nd sentence).

25. Regarding Claim 10, Arnold discloses a statistical analysis (see col. 8, lines 58-65). Arnold does not disclose the statistical analysis of the variation between pre-dose and post-dose ECG signals. DePasquale discloses statistically analyzing this variation (see col. 2, lines 43-48). Thus, it would be obvious to one of ordinary skill in the art at the time of the invention to perform a statistical analysis of any measurement acquired from an ECG signal in order to understand which variations are significant and which ones are attributed to noise and other sources of error.

Conclusion

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


27. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NNP
7/17/06


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Supervisory Patent Examiner
Art Unit 3766